

**The Effectiveness of the 3A-OR Very Brief Tobacco Cessation Intervention in Primary
Care: A Multicenter Pragmatic Trial Protocol**

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ABSTRACT

Introduction: Türkiye is far from the World Health Organization's target of reducing tobacco use prevalence by 30% by 2025. Most tobacco users consider quitting, and most have attempted to quit at least once. However, the success rate of quitting on one's own is quite low. Studies demonstrating that very brief tobacco cessation interventions delivered by healthcare professionals increase cessation rates have almost entirely been conducted in hospital settings. The aim of this trial is to investigate the effectiveness of implementing the 3A-OR very brief tobacco cessation intervention in routine primary care family medicine practice on the success of tobacco cessation.

Methods/design: This protocol describes a two-arm, multicenter pragmatic trial for adolescent and adult tobacco users. The project will be carried out in family health centers in 21 study sites across the 12 statistical regions of Türkiye. In the intervention arm, volunteer family physicians will implement the 3A-OR very brief tobacco cessation intervention to their patients as part of their routine clinical practice. The intervention consists of the following steps: 'asking patients about their tobacco use status', 'assessing users' motivation to quit', 'advising quitting based on their motivation status', 'offering cessation assistance', and 'recording information regarding patients' tobacco use status and repeating the intervention at each patient contact'. Routine practice in family health centers will constitute the control group. Data will be collected using standard questionnaire forms at baseline and during follow-up interviews at 3, 6, and 12 months. Tobacco cessation rate and increase in smokers' motivation were the primary outcomes of the trial.

Discussion: If the 3A-OR very brief tobacco cessation intervention is found to be effective, the results of this trial will provide evidence that will encourage the widespread use of the intervention in primary care family health centers. The study results are intended to be disseminated through the Family Medicine Academy Association website, conference presentations, and scientific publications.

INTRODUCTION

Tobacco use remains a significant public health problem worldwide. The World Health Organization (WHO) has reported in its 2024 report that the rate of tobacco use among adolescents and adults worldwide is 21.7% (1). According to the Global Adult Tobacco Survey (GATS 2016) data for Türkiye, the prevalence of tobacco use among those aged 15 and older in our country is 31.6% (2). According to the WHO report, Türkiye is among the European countries with the highest tobacco consumption rates, with a projected prevalence of 30.5% for 2020 (1).

Thanks to the efforts and measures taken by the WHO and its member countries, which signed the Framework Convention on Tobacco Control (FCTC) in 2003, the prevalence of tobacco use among the population aged 15 and over has been steadily decreasing globally over the past quarter century. (3). According to WHO data, the prevalence of tobacco use decreased from 32.7% in 2000 to 21.7% in 2020. The WHO has projected a 19.8% prevalence rate of tobacco use for 2025 and an 18.4% rate for 2030. This downward trend over the last quarter century is observed in both women and men. The WHO's target for member countries to reduce tobacco use prevalence by 30% by 2025 compared to 2010 levels is projected to be achieved at 25% globally.

Türkiye, which enacted its first law to prevent the harms of tobacco products in 1996, ratified the WHO Framework Convention on Tobacco Control in 2004. Subsequently, in parallel with the WHO FCTC and MPOWER measures, the National Tobacco Control Program and Action Plan was implemented in 2006 (3).

In the first period of the action plan, significant improvements were achieved in indicators related to tobacco use. The prevalence of tobacco use, which was 31.2% in the GATS 2008, decreased to 26.9% in the GATS 2012. The rate of smokers considering quitting has increased. However, in 2016, the opposite was observed in the data. While the prevalence of tobacco use has increased again (31.6%), the rate of smokers considering quitting has decreased (3). The prevalence of tobacco use is similarly high according to the results of the 2019 and 2022 Türkiye Health Surveys (31.3% and 32.1% respectively) (4).

As a result, Türkiye appears to be far from the WHO's target of reducing tobacco use prevalence by 30% by 2025. According to the World Health Organization's 2024 report, Türkiye is among the few countries where tobacco use prevalence has remained unchanged or changed very little (1).

The renewed increase following the short-term positive impact attributed to public health measures has been partly explained by the failure to maintain these measures and the increase in the economic power of the people (3). Based on this, it is recommended that the public health measures taken within the framework of MPOWER strategies be increased and continued.

On the other hand, most tobacco users consider quitting, and most have tried to quit at least once (5,6). However, the success rate of quitting on one's own is quite low. One of the MPOWER strategies involves helping smokers quit tobacco use. Therefore, in addition to general public health measures, efforts by healthcare professionals to directly help smokers quit can also contribute to the fight against tobacco use.

In many countries, especially in economically developed ones, programs have been established to support smokers who want to quit, and specialized cessation counseling clinics exist. With the rapid increase in the last six months, there are now more than 1,250 such centers in our country (7). Although nearly four million smokers have benefited from these services in the last 15 years, these centers are still underutilized by smokers, and their contribution to the fight against tobacco use remains limited. A study conducted in our country showed that 17% of smokers were able to access Smoking Cessation Clinics and only 1.6% were able to quit tobacco use for more than six months with the help of these centers (8).

As can be seen, the effectiveness of public measures, which intensified and increased in the first quarter of the last century in our country in combating tobacco use, has been limited, and the contribution of specialized cessation centers has also been minimal. Therefore, assessing tobacco use habits during routine patient consultations in daily practice and continuing the fight against tobacco use at the individual level is becoming increasingly important. In this sense, primary healthcare centers are the most suitable settings, and the WHO recommends integrating brief interventions into primary healthcare delivery (9).

In most countries, primary care providers identify tobacco users, advise them to quit, and offer support to help them quit (10). The WHO recommends brief cessation interventions that can be used particularly by primary care physicians. These interventions have been shown to be effective in primary care settings (6,11,12). A Cochrane meta-analysis found that brief interventions to quit increased the success rate of quitting among smokers by as much as their self-quitting rate (2-3%) (12). Therefore, most clinical guidelines recommend identifying

smokers, providing brief quitting advice, offering behavioral support and pharmacotherapy to help quit, and developing brief interventions using the 5A approach (13).

Although their effectiveness has been demonstrated, these interventions take up to 20 minutes to implement. Therefore, the rate at which family physicians use brief interventions in primary care settings with high patient load is low. Tobacco use screening and counseling practices vary across settings (5,14,15). In our country, the rate of tobacco cessation advice provided by healthcare professionals is around 40% (16,17). The most important reasons reported for this are time constraints and healthcare professionals feeling insufficient themselves in this regard (18,19).

Therefore, to increase its applicability in routine primary care patient consultations, very brief clinical interventions lasting no more than three minutes have also been suggested (11,12,20). The limited number of studies investigating the effectiveness of these interventions, developed based on the 5A approach, have reported conflicting results. Two studies with small sample sizes found higher cessation rates in the intervention group, but this difference was not statistically significant (11,20). Another study with a much larger sample size found that a very brief clinical intervention significantly increased cessation success (12). On the other hand, a study conducted in our country showed that a very brief intervention highlighting the harms of mothers' tobacco use on their children's health was effective in helping them quit tobacco use (21). A meta-analysis involving 13 randomized controlled trials studying very brief interventions lasting less than three minutes has recently been published (22). This systematic review found that very brief interventions increased tobacco cessation rates in periods shorter or longer than six months.

These randomized controlled trials investigating the effectiveness of very brief interventions are predominantly explanatory in nature and almost all have been conducted in hospital settings. Therefore, pragmatic controlled trials investigating the effectiveness of very brief clinical interventions used in routine practice in primary care settings are needed. Furthermore, although the interventions applied in these trials were developed based on the 5A approach, they do not take into account the smokers' motivations for quitting.

However, it is known that being ready to develop healthy behaviors strongly increases success rates (23). Tailoring tobacco cessation counseling according to the smoker's motivation and readiness to quit has positive outcomes in terms of the effectiveness of the

counseling (24). Targeted counseling (based on motivation level) is considered standard practice in the management of tobacco addiction (25).

Recently, a pragmatic randomized controlled trial investigating the effectiveness of a very brief clinical intervention developed using this approach in PC was conducted in our country (26). The 3A-OR intervention primarily assesses the smoker's motivation to quit and tailors counseling accordingly. In this study, which evaluated cessation success with a small sample size and only three months of follow-up, higher cessation rates were obtained in the intervention group, but the difference was not statistically significant. The intervention is effective in creating positive changes in motivation within the smokers. In conclusion, the researchers recommended that pragmatic trials with longer follow-up periods, larger sample sizes, and multicenter be conducted to demonstrate the effectiveness of their very brief clinical interventions in PC settings (26).

Based on this, this multicenter pragmatic randomized controlled trial was designed. The aim of this trial is to investigate the effectiveness of using the 3A-OR very brief clinical intervention on smoking cessation success in routine primary care family medicine practices.

METHODS

Study design

This protocol describes a two-arm, multisite, pragmatic randomized controlled trial for adolescent and adult tobacco users.

The project will be implemented in family health centers across the country. Twenty-one study sites have been selected from 12 statistical regional units of Türkiye.

Participants

Smokers meeting the following criteria will be included in the study:

- 1) Being aged 15 years and older (including pregnant and breastfeeding women);
- 2) Having used any tobacco product at least once daily within the last month;
- 3) All smokers, regardless of their intention to quit tobacco use;
- 4) Providing a phone number for follow-up;
- 5) Being able to read and speak Turkish;
- 6) Signing the informed consent form.

The exclusion criteria for the study are as follows:

- 1) Using tobacco products less than once per day;
- 2) Having made an attempt to quit tobacco use within the last month;
- 3) Having impaired cognitive functions;
- 4) Having participated in another study on tobacco use within the past year.

Recruitment procedures

Since the control group of the trial will consist of the existing routine practice of assessing patients' tobacco use habits in family health centers, the family physicians for the intervention group will be selected purposefully and on a voluntary basis. For this purpose, family physicians practicing at family health centers in the study sites will be invited to participate in the trial. Those who agree to participate will be included in the study and will form the intervention arm of the trial. Before starting the trial, participating family physicians will be informed about the trial and the intervention. They will also be given informational materials and patient brochures about tobacco use and quitting.

At each study site, a face-to-face meeting will be held with family physicians who have agreed to participate in the intervention group. These meetings will discuss what they

have already done regarding tobacco use and quitting, what problems they are encountering, what they can do within a limited time during routine consultations with the patients, and what kind of support they need regarding the issue. The aim of this discussion is to involve volunteer family physicians in the process and increase their willingness to participate. Following this discussion, it will be determined whether they are ready and willing to incorporate a more structured, very brief intervention (lasting less than two minutes) regarding the assessment of their patients' tobacco use habits and providing advice to smokers into their routine patient consultations. At the end of the meeting, those who remain committed to participating in the intervention arm of the study and who are ready and willing to make appropriate adaptations in their routine clinical practice will be included in the process.

Regardless of their prior routine practices regarding assessing patients' tobacco use habits and providing advice to tobacco users, family physicians in the intervention arm will be asked to begin implementing the 3A-OR very brief clinical intervention in their routine patient consultations starting the very next day. Thus, family physicians involved in the intervention will primarily have integrated the intervention into their routine patient consultations at primary care family health centers.

One additional family health center closest to each family health center where the family physicians in the intervention arm work will be selected, and smoking patients of the family physicians working at this center will form the control group of the trial. These physicians will not be contacted or informed about the intervention. Their consent will only be obtained to conduct a survey with their patients in the waiting room. It is anticipated that during the data collection period, these physicians will continue their existing practices, if any, regarding assessing their patients' smoking habits and providing advice to smokers.

Family physicians and other family health center staff will not assume any duties or responsibilities in data collection or follow-up. Initial data will be collected in the waiting room on randomly selected days without informing the physicians previously, by a researcher at each study site.

Smokers who visit family health centers for any reason will constitute the study population. No individual invitation will be sent to participants. Following their routine interview with their family physician, patients will be asked if they smoke or use any tobacco products. Smokers aged fifteen and over who meet the inclusion criteria will be invited to

participate in the study. Those who are willing to participate will be recruited to the study. Patients of the physicians implementing the intervention will be included in the intervention group, while patients of other physicians at the designated closest health centers will be assigned to the control group. By selecting different family health centers for the control group, the likelihood of family physicians in the control group learning about the intervention's content and altering their routine practices will be minimized. Informed consent from participants in the intervention group will be obtained after the intervention has been implemented on them. Those who agree to participate will be briefly informed about the study and asked to sign an informed consent form.

Except for a one-hour training session providing information about the study and the intervention, no additional contact will be established with the physicians delivering the intervention. The intervention will allow for individual implementation and physicians' performance will not be evaluated

Intervention

The 3A-OR very brief tobacco cessation intervention, whose effectiveness is investigated in primary care settings, consists of five steps. The first step involves ascertaining the patient's tobacco use status; the second step assesses the user's motivation to quit; then, assistance is offered by advising to quit tobacco use; and finally, information regarding the patient's tobacco use status is recorded in their file, and the intervention is repeated at each patient visit. More detailed information about the intervention is given in **Table 1**.

Data collection tools

Data will be collected using structured, standardized survey forms. The survey forms have been developed taking into account the forms used in other studies reported in the literature.

Initial Data Collection Form: The form consists of 12 questions designed to determine the sociodemographic characteristics of the participants at the time of application, the presence of any physician-diagnosed chronic diseases, and their perceptions regarding their health status (Appendix 1).

First-Week Data Collection Form: The form consists of 10 questions designed to determine the tobacco use characteristics of the participants, such as the age at which participants started using tobacco, previous quit attempts, and the number of these attempts (Appendix 2). The

form also includes the Short Form of the Fagerström Test for Nicotine Dependence, which consists of two questions and assesses physical nicotine dependence.

Follow-up Data Collection Form: The form consists of six questions regarding tobacco use, which will be collected through telephone interviews with participants at 3, 6, and 12 months (Appendix 3).

Data collection

A researcher from each study center will administer face-to-face surveys in the waiting room to smokers who agree to participate in the study. Patients will be invited to participate in the study sequentially until the targeted sample size is reached for both the family physicians in the intervention group and the family health centers in the control group. During the initial interview, only data regarding participants' demographic and medical characteristics will be collected. Information on participants' smoking habits and motivation to quit smoking will be collected a week later via telephone by a second researcher, unaware of which group the patients belong to. The second researcher will also conduct follow-up interviews with participants by telephone three, six, and twelve months after the initial interview to gather updated information regarding their smoking status, quitting attempts, and motivation to quit.

Family physicians in both the intervention and control groups will not assume any responsibility for the collection of study data. Physicians who will not know which of their patients were included in the study will also not be asked to conduct scheduled follow-up visits with the participants. If participants visit again to their physicians for any reason within the one-year study period, physicians are expected to continue their routine practices without knowing patients' study participation.

Randomization

The study is based on a pragmatic randomized controlled trial design. Pragmatic trials, unlike explanatory trials conducted in ideal settings, evaluate inputs and outputs that occur in accordance with the natural course of events. Participants will be randomized according to the group of family physicians they interviewed. Physicians who volunteer to participate in the trial will form the intervention arm, and physicians from the nearest other family health center will form the control arm. Smokers will be assigned to either the intervention or control groups according to which group their family physicians belong to.

Blinding

Since the smokers participating in the study will not know the position of their family physicians, they will also not know which group they belong to. The researcher collecting the initial data will identify the groups of smokers, code each participant, and naturally have knowledge of the smokers' groups. However, researchers collecting the follow-up data will be unaware of the groups of smokers.

Outcomes

Dependent variables

The primary dependent variables: 1) Patient-reported success in quitting tobacco use among smokers in the intervention and control groups at the end of three, six, and twelve months, and 2) Changes in motivation to quit among smokers who have not quit tobacco use. For successful tobacco cessation, the key criterion will be that the individual has not used tobacco for at least the last 7 days at the three-month follow-up, at least the last 15 days at the six-month follow-up, and at least the last month at the one-year follow-up. Even a single instance of using any tobacco products within the specified periods will be considered a "failure."

The secondary outcomes: 1) Attempting to quit tobacco use, 2) Self-medication status, 3) Applying to smoking cessation counseling clinics, 4) Predictors of successful quitting.

Independent variables

The sociodemographic features, medical characteristics, and baseline characteristics related to tobacco use stated in the data collection form will constitute the independent variables of the study.

Determination of sample size

The sample size for the mixed models, which are the main analyses to be used in the study, is determined through simulations. However, this method requires knowing too many parameters beforehand and is not practical. Therefore, rules of thumb have been defined in the literature. For generalized linear mixed models, it has been stated that having 50 second-level participants, with 50 participants in each of these 50 levels, will ensure sufficient power. In linear mixed models, it has been shown that a ratio of 30/30 is sufficient. In our study, it was planned to take 50 measurements from each study site for 21 intervention groups and 21 control groups, which is at the level recommended in the literature (27).

Statistical analysis

Descriptive data will be reported as frequency (percentage) for categorical variables, mean \pm standard deviation for normally distributed continuous variables, and median (interquartile range) for non-normally distributed continuous variables.

Prior to univariate analyses, parametric test assumptions will be checked using normality histograms and linear relationship scatter-dot plots. In the presence of heteroscedasticity, adjusted test values (robust estimates) will be reported.

Assumptions prior to multiple tests will be checked using post-hoc residual plots. The Generalized Linear Mixed Model will be used to analyze tobacco cessation success, while the Linear Mixed Model will be used to analyze the increase in motivation to quit tobacco. Participant IDs and study sites will be included as random effects in mixed models. This will allow for the control of other unmeasurable factors that affect study outcomes between study sites. All analyses will be performed using the R 4.5.0 program. For univariate analyses, the “rstatix v 0.7.3” package will be used, for mixed models the “lme4 v 1.1-38” package, and for visualization the “ggplot2 v 4.0.1” package. The significance level will be considered to be $p < 0.05$.

Those who could not be reached during follow-up will be considered as not having quit tobacco use and as having unchanged motivation in the analyses (intention-to-treat analysis).

Ethical principles

Ethical approval for the research will be obtained from the Non-Interventional Studies Ethics Committee of Aydın Adnan Menderes University Faculty of Medicine (Date: January 20, 2026; Protocol No: 2025/381; Decision No: 31), and administrative permissions for conducting the study in family health centers will be obtained from all Provincial Health Directorates (or directly from the Ministry of Health).

Individuals included in the research sample will be informed of the purpose of the study and their written consent will be obtained for participation. Their telephone numbers and all other personal information will strictly be kept confidential.

It will be assumed that physicians in the intervention arm provide very brief tobacco cessation advice to all their patients. Physicians in the control group may have discussed tobacco use and cessation with their patients as part of routine patient-physician interactions.

The study design was checked using the CONSORT and PRECIS-2 (Pragmatic to Explanatory Continuity Indicator Summary) tools (28,29).

DISCUSSION

This study is a multisite, large-sample pragmatic trial investigating the effectiveness of the 3A-OR very brief tobacco cessation intervention in primary care.

Unlike other very brief interventions, the 3A-OR model is motivation-oriented. Our intervention prioritizes identifying the user's motivation to quit smoking and is flexible accordingly. Our approach is based on the evidence that directing tobacco cessation counseling according to the user's motivation and readiness to quit increases the effectiveness of the counseling, and that targeted counseling is considered standard practice in the fight against tobacco dependence (23,25).

Tobacco users participating in the trial are not randomized prior to the intervention. Participants are randomly assigned to groups based on whether the physicians they consult are in the intervention or control arm. The intervention is embedded within the physician's routine practice, and the physician will begin applying it to all patients, regardless of whether they are included in the study, and is expected to continue applying it even after the study period ends. The physicians involved in the intervention will not know which of their patients will be included in the study. Therefore, participant consent will be obtained after the intervention, based on whether or not the smoker wishes to participate in the study.

The WHO's most recent guideline clarifies its recommendation that all healthcare professionals should provide brief tobacco cessation advice. The 5A recommendations, which can vary in duration, have been clarified as very brief interventions that can be delivered within 30 seconds to 3 minutes. The WHO bases these recommendations on Cheng's meta-analysis (22).

Despite the efforts made in our country over the last 30 years, especially intensified in the last two decades, serious challenges are still being experienced in the fight against tobacco. Therefore, the Turkish Ministry of Health is seeking new approaches within the scope of the fight against tobacco use and is currently working on updating the national guideline, the 'Handbook on Combating Tobacco Dependence (30). In addition to the measures taken and continued to be implemented within the scope of public health, it aims to ensure the active participation of physicians within the healthcare system, particularly family physicians working in primary care, in the process. Apart from brief quitting recommendations, the provision of intensive counseling services in primary care to support users who are considering quitting tobacco use is also being considered.

If the 3A-OR very brief tobacco cessation intervention is found to be effective in primary care settings, the results of this trial will provide evidence for the national guideline. This will thus enable the widespread use of the intervention in primary care family health centers.

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Appendix 1.

Table 1. Steps of the 3A-OR Very Brief Tobacco Cessation Intervention

3A-OR Very Brief Tobacco Cessation Intervention			
<i>Steps</i>		<i>Smokers in the “Precontemplation” stage</i>	<i>Smokers in the “Contemplation” or “Preparation” stage</i>
1 (A)	ASK	The patient may state in the history that they use a tobacco product. If the patient does not mention anything about tobacco use during the course of the consultation, the physician asks within the scope of assessing habits: “Do you use cigarettes or any tobacco product?” Those who do not use are congratulated. The process continues with those who use.	
2 (A)	ASSES	The physician evaluates the smoker’s motivation to quit tobacco use: “Are you considering quitting tobacco use?” The smoker may be in the precontemplation, contemplation, or preparation stage.	
3 (A)	ADVISE	“Using tobacco is harmful to health. Tobacco causes many diseases such as cardiovascular diseases, COPD, and cancer. One out of every two tobacco users dies due to tobacco-related causes. Quitting tobacco use is the most important action you can take for your health. I strongly recommend that you quit tobacco use.”	“I congratulate you on your intention to quit tobacco use. Using tobacco products is harmful to health. One out of every two tobacco users dies due to tobacco-related causes. Quitting tobacco use is the most important action you can take for your health. I recommend that you implement your intention as soon as possible.”
4 (O)	OFFER ASSISTANCE	“If you would like to talk about your tobacco use, I can give you a separate consultation appointment (if the smoker accepts, an appointment is given as soon as possible). If you consider quitting, I can always assist you personally or refer you to tobacco cessation centers.” (The patient is provided with information about tobacco and tobacco cessation centers where they can receive support, or a brochure containing this information may be given.)	“I can help you during this process. If you wish, I can give you a separate appointment. You may apply to a tobacco cessation center to receive support (a brochure containing information about Smoking Cessation Clinics in the nearby area may be provided). I can make an appointment for you whenever you wish.”
5 (R)	RECORD and	The family physician records the patient’s information regarding tobacco use	

	REPEAT	status. At each subsequent contact, the physician reintroduces the topic from where it was left and repeats the intervention.
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Appendix 2.

BASELINE DATA COLLECTION FORM

Participant code:

Did you talk with your physician inside about tobacco use? 1) No 2) Yes

Demographic and medical characteristics

Age:

Gender: 1) Female 2) Male

Marital status: 1) Single 2) Divorced/Widowed 3) Married

Educational status: 1) Less than 9 years 2) 9–12 years 3) More than 12 years

Income level (family):

1) Less than 30,000 TL 2) Between 30,000–100,000 TL 3) More than 100,000 TL

Perceived income:

1) Income less than expenses 2) Income equal to expenses 3) Income greater than expenses

Employment status:

1) Not actively working (in an income-generating job) 2) Actively working

Occupation (Retirees will be included within occupational groups):

1) Civil servant 2) Worker 3) Farmer 4) Self-employed (tradesperson) 5) Employer

6) Student 7) Housewife 8) Unemployed 9) Other:

Alcohol use: 1) Does not use 2) Irregular use 3) Regular use

Substance use: 1) None 2) Present

Chronic disease: 1) None 2) Present

How do you evaluate your own health? 1) Very poor 2) Poor 3) Moderate 4) Good 5) Very good

Appendix 3.

WEEK ONE DATA COLLECTION FORM

Participant code:

Tobacco use characteristics

Type of tobacco used: 1) Cigarette 2) Waterpipe 3) Pipe/cigar 4) Other

Age of initiation of tobacco use:

Duration of tobacco use (pack/year):

Daily amount of tobacco use (number/day):

Previous quit attempt: 1) None 2) Present (How many times:)

Another tobacco user at home: 1) None 2) Present

Another tobacco user at workplace/school: 1) None 2) Present

Motivation to quit tobacco use: 1) Precontemplation 2) Contemplation 3) Preparation

Short Fagerström score: ()

How many minutes after waking do you smoke your first cigarette?

- A. Within the first 5 minutes after waking;
- B. Within 6–30 minutes;
- C. Within 31–60 minutes;
- D. After 1 hour

How many cigarettes do you smoke per day?

- A. 10 cigarettes or less;
- B. Between 11–20 cigarettes;
- C. Between 21–30 cigarettes;
- D. 31 cigarettes or more

How difficult is it for you to quit tobacco use (1. Least ... 10. Most)?

1 2 3 4 5 6 7 8 9 10

Appendix 4.

FOLLOW-UP DATA COLLECTION FORM

Participant code:

Tobacco use status: 1) Using 2) Quit

Change in smoking amount according to the individual: 1) Increased 2) No change 3) Decreased

Motivational stage (for those who continue to use tobacco):

1) Precontemplation 2) Contemplation 3) Preparation

Attempt to quit tobacco use: 1) No 2) Yes

Self-use of medication: 1) No 2) Yes

Application to smoking cessation outpatient clinics: 1) No 2) Yes

Appendix 5.

CONSORT

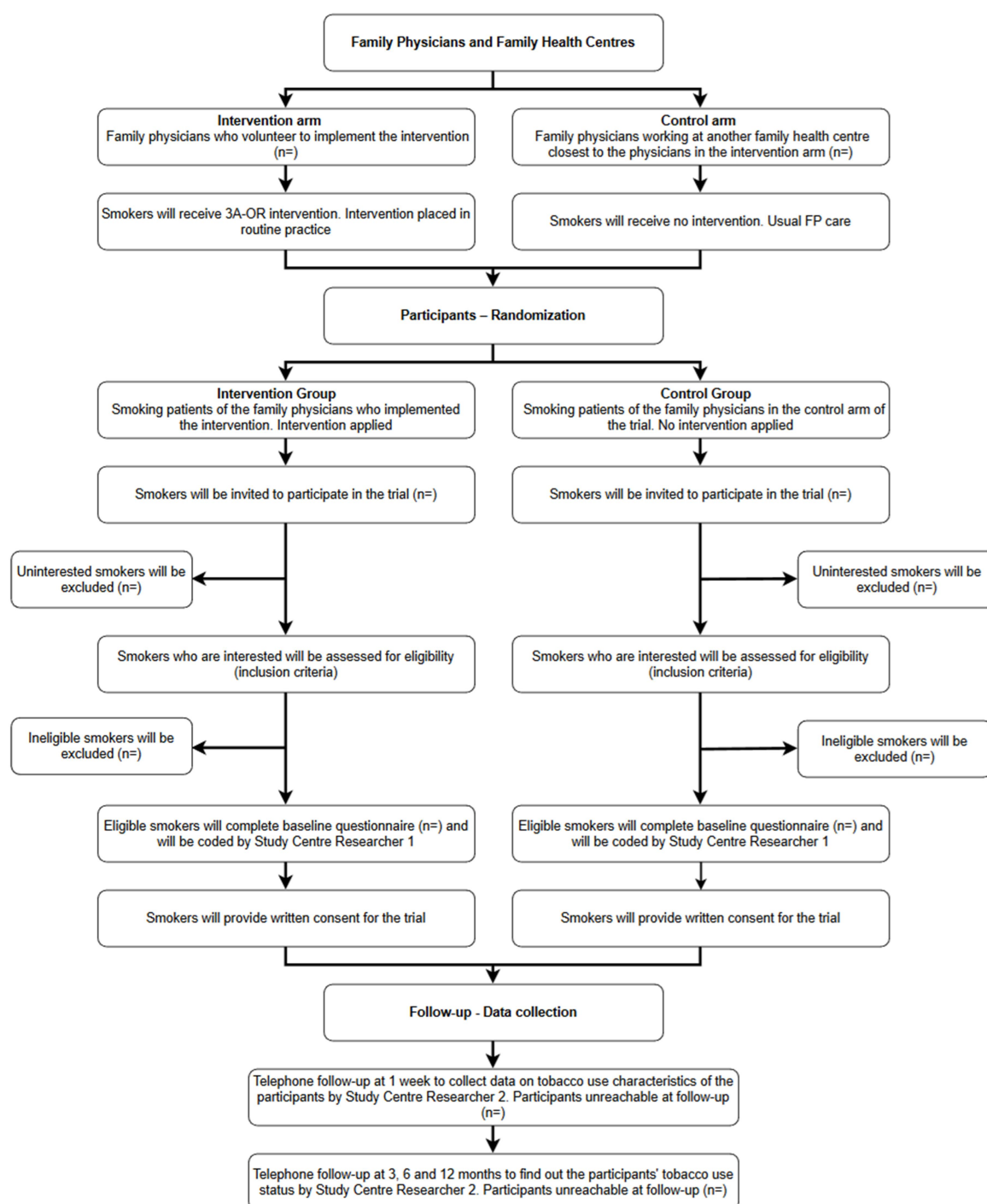


Figure 1. Recruitment and study flowchart

Appendix 6.

PRECIS 2 Control

Our trial has been designed in a rather pragmatic approach according to The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) assessment tool. First of all, family physicians in intervention group have integrated the intervention as a part of their routine practice of patient consultations. Family physicians and other health staff did not have any duties or responsibilities in the collection of study data and follow-up. Baseline and follow-up data have been collected entirely by one of the researchers on randomly selected days to visit without the ignorant of the participating physicians. No special invitation has been made to the participants. Smokers among the patients who completed their regular interviews with their family physicians have been invited to participate in the study at waiting room. No randomization has been made before the implementation of the intervention. Smoking patients of the physicians implementing the intervention have been included in the intervention group, and smoking patients of other physicians who continued their regular clinical practices in the health center have been included in the control group. Apart from informing about the intervention and the study in a one-hour training session, no further contact has been made with the physicians implementing the intervention. Individualization has been permitted to the physicians in the implementation of the intervention, and their performance has not been evaluated. We believe that our trial is not pragmatic enough in only one PRECIS 2 domain. Although the trial has been conducted in primary care setting, the sample did not fully represent of all FHCs where the intervention could be implemented in routine patient visits.